October 6, 2020

Brent C. Morse, DVM
Department of Health and Human Services
Rockledge, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Morse,

Under provision of IV.F.3 of the Animal Welfare Assurance Policy and as the Institutional Officer at the University of Utah (U of U), I am providing OLAW with a full explanation of circumstances in regard to an adverse event.

Name of Institution: University of Utah
Assurance Number: A3031-01

The Principal Investigator notified the IACUC of a potential serious adverse event via an Event Notification form concerning the below mentioned protocol on September 27, 2020. The IACUC Director notified the IACUC Chair and the Institutional Veterinarian of the potential adverse event on September 27, 2020. It was discussed that this event would be reviewed at the next convened IACUC meeting on September 30, 2020.

The following is a summary of the adverse event:

1. Protocol number: 20-09011
2. Protocol title: Functional Remodeling of the Tripartite Synapse in the Dorsolateral Striatum during Development of Habitual Drug Seeking
3. Funding agency: NIH/NIDA
4. Animal species: Rat
5. Age of animal(s): post-natal day 70
6. Number of animals involved in the event: 2
7. Date(s) that the event occurred: September 27, 2020
8. Overview of the adverse event (as provided by the Principal Investigator):
At the end of each self-administration session, rats are given an IV infusion of Baytril. I had filled the syringes, and when animal #48 was taken out of the chamber, I gave him what I thought was Baytril. He appeared to have a seizure momentarily, and then gasped a few times and then died (stopped breathing, I could not feel a heartbeat). I paused, and wondered if the infusion of Baytril, in clearing the jugular vein catheter of cocaine resulted in too much cocaine right after the rat had finished self-administering cocaine. Since the other animal (#43) was a yoked-saline control, I knew this wouldn't be an issue, so I took it from its cage and gave it the syringe with what I thought was its Baytril. It too, immediately, appeared to have a brief seizure, gasped a few times, and died. I then realized that it had to be that I had made a mistake and not filled the syringes with Baytril. Both the Baytril and 70% EtOH are in 50 mL Falcom tubes with purple tops, albeit at opposite ends of the tube holder. While they are labeled, I must have inadvertently grabbed the EtOH tube, rather than the Baytril, when I prepared the four syringes for this cohort of animals. I discarded the remaining two syringes and prepared new syringes from the Baytril tube. The two remaining animals were treated without incident. Animal Numbers 48 and 43 were given bilateral thoracotomies and placed in a double plastic bag in the freezer.

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9. Was there inadvertent pain involved in the adverse event (more than momentary)?:
   I assume so.

10. Describe the corrective actions to avoid future problems:
    I will have our lab order tubes with different color lids to use for the Baytril, so that the tube/lid cover identify the compound. Further, we will put a second tube rack on the counter so that the Ethanol is kept separately and away from the drugs being administered to animals.

11. Provide a conclusion:
    Two rats on study died due to an error on the part of the PI, who filled the syringes with the wrong substance. To avoid this in the future, different colored tubes and a separate holding rack will be used to keep 70% EtOH away from drugs administered to the rats.

The IACUC, at a convened meeting on September 30, 2020, discussed the details of the event and the corrective actions provided by the Principal Investigator as written above.

The committee determined that this was a serious adverse event due to an unfortunate mistake and that it should be reported to the Office of Laboratory Animal Welfare (OLAW). The committee agreed with the corrective actions as described by the Principal Investigator. No additional action was requested by the committee. The committee voted unanimously to report the adverse event and agreed with the corrective actions, and that no further action was required.

In conclusion, the committee determined that this is a serious adverse event and will be reported to the regulatory agency of the Office of Laboratory Animal Welfare (OLAW) since it is federally funded. The Principal Investigator was requested to report this to the agency that is funding this research.

The IACUC Director and the IACUC Chair met with the Institutional Official on October 6, 2020 and determined that the corrective actions presented by the Principal Investigator were adequate and no additional action is required.

Sincerely,

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Vice President for Research
Institutional Official

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